K051553

JUL 7 - 2005

FUJIFILM

I&I - Imaging & Information

FUJIFILM MEDICAL SYSTEMS USA, INC.

419 WEST AVENUE
STAMFORD, CT 06902
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510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, FUJIFILM Medical Systems, USA, Inc. herewith submits a 510(K) summary for the following device.

Submitter Name / Address:	FUJIFILM Medical Systems, USA, Inc. 419 West Avenue Stamford, CT 06902
Contact Person / Tel No.:	Rob Berry Director of Quality Assurance and Regulatory Affairs
Date Summary Prepared:	March 28, 2005
Establishment No.:	2443168
Trade/Proprietary Name:	Fuji Synapse Workstation Software
Common/Usual Name:	Medical Image Processing Workstation
Classification Name:	Picture archiving and communications system
Class/Panel:	Class II, 90-LLZ, 21CFR 892.2050
Predicate Device(s):	CR Console (Flash IIP), Fuji Medical Systems Light Beam Workstation, Amicas, Inc. IDS5/mx.net Workstation, Sectra Imtec AB

Device Description:

The Synapse Workstation provides viewing and manipulation of radiological data including images, reports, patient status, and clinical information.
The workstation utilizes a folder structure providing easy navigation and organization of images, studies, documents, etc. that most users are familiar with from Microsoft Explorer and other Windows applications. The workstation contains workflow scripting and hanging protocols designed to maximize productivity and allow each user to tailor the workstation operation to their individual needs.
In addition to common image manipulation functions such as window/level and window/width variation, magnification, density value, etc., the Synapse Workstation provides more advanced image processing, including processing of CR and CT images. The Synapse Workstation does not provide any advanced image processing for DICOM MG "For Presentation" mammography images.

Intended Use:

Fuji Synapse Workstation Software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with Fuji Synapse PACS. The Fuji Synapse Workstation is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The Synapse Workstation can process medical images from the following modality types: plane X-ray radiography, X-ray computed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Fijifilm Medical Systems USA, Inc.
% Mr. Jeffrey D. Rongero
Senior Project Engineer
Conformity Assessment Services
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709

Re: K051553
Trade/Device Name: Fuji Synapse Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 28, 2005
Received: June 29, 2005

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): _____

Device Name: **Fuji Synapse Workstation**

Indications For Use:

Fuji Synapse Workstation Software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with Fuji Synapse PACS. The Fuji Synapse Workstation is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The Synapse Workstation can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities.

The Synapse Workstation may be used for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible, displays. Synapse does not provide spatial frequency enhancement, dynamic range control, or multi-objective frequency image processing for DICOM MG "For Presentation" mammography images.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K051553